

REMARKS

Applicant respectfully requests reconsideration.

Claims 12, 15-17 and 38-54 were previously pending in this application.

Claim 12 has been amended to remove the words “or preventing” from the preamble.

Claims 41, 43, 46, 49, 50 and 51 are currently withdrawn from consideration.

As a result, claims 12, 15-17, 38-40, 42, 44, 45, 47, 48 and 52-54 are pending for examination with claim 12 being an independent claim.

No new matter has been added.

Telephone Interview Summary

Applicant thanks Examiner Foley for conducting a telephone interview with Applicant's representative on April 17, 2008. The telephone interview was conducted with Examiner Foley because Examiner Minnifield was unexpectedly unavailable for the call. During the interview, the outstanding Office Action was discussed.

Rejection under 35 U.S.C. §112

Claims 12, 15-17, 38-40, 42, 44, 45, 47, 48 and 52-54 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

The Examiner has apparently reiterated many of the same bases for rejection as in the previous Office Action and in doing so has not taken into consideration the claim amendments and arguments put forth by Applicant in the last filed response. Applicant calls the Examiner's attention specifically to the previous amendments to claim 12 to recite a specific formula of CG motif. In particular, the amended claim recites that the CpG immunostimulatory nucleic acids comprise a 5' N₁X₁X₂CGX₃X₄N₂ 3' sequence wherein X₁ and X₂ are both purines and X₃ and X₄ are both pyrimidines, and N₁ and N₂ are nucleic acid sequences composed of 0-25 nucleotides each. These nucleic acids are 8-100 nucleotides in length.

The written description requirement is satisfied if the invention is described in “sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66

USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. As the Examiner acknowledges on page 5 of the Office Action, possession of the invention can be shown in a number of ways including “describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.” Applicant asserts that the specification describes distinguishing identifying characteristics of the claimed invention. The claimed invention relates to a method for treating an asthmatic event in a hypo-responsive subject, wherein the hypo-responsive subject is refractory to an asthma/allergy medicament. Support for these features of the claimed invention can be found throughout the specification, at least on page 6 lines 16-19 and page 7 lines 4-5. The claimed invention further involves administration of a CpG immunostimulatory nucleic acid which contains a specific sequence motif described in claim 12. Support for this sequence motif can be found in the specification at least on pages 33-35 and in the sequences listed in Table 1 on pages 12-33. Specifically, page 34 lines 24-25 describes the sequence motif of claim 12 wherein X_1 and X_2 are both purines, and X_3 and X_4 are both pyrimidines. Page 34 lines 19-20 describes the claim limitation that N_1 and N_2 are both about 0-25 nucleotides each. The length range of 8-100 nucleotides for the CpG immunostimulatory nucleic acid is found at least on page 35 lines 20-21. Claims 53 and 54 add further limitations to the sequence motif of the CpG immunostimulatory nucleic acid. Support for these limitations can be found in the specification at least on pages 34 lines 23-24 and in the sequences listed in Table 1 on pages 12-33. The specification therefore provides sufficient distinguishing identifying characteristics of the claimed invention to demonstrate that Applicant was in possession of the claimed invention at the time of filing.

The claimed invention relates to administering a genus of immunostimulatory nucleic acids that share a common sequence motif. The written description of a genus can be satisfied in a number of ways including by “sufficient description of a representative number of species by actual reduction to practice, ...disclosure of relevant, identifying characteristics,...by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus” (MPEP 2163). The claimed invention relates to a genus of CpG immunostimulatory nucleic acids described in claim 12. Further sub-genera are described in claims

53 and 54. Applicant has provided structural features of the claimed genus of nucleic acids. The CpG immunostimulatory nucleic acids of this genus comprise a 5' N₁X₁X₂CGX₃X₄N₂ 3' sequence motif wherein X₁ and X₂ are both purines and X₃ and X₄ are both pyrimidines, and N₁ and N₂ are nucleic acid sequences composed of 0-25 nucleotides each. These nucleic acids are 8-100 nucleotides in length. The immunostimulatory activity of these nucleic acids is attributable to the CG motif. Applicant further provides in the specification many representative examples of species that belong to the claimed genus. The specification provides 218 species embraced by claim 12, of which 102 species are embraced by claim 53, of which 64 species are embraced by claim 54. Specific examples of SEQ ID numbers for each of these genera are detailed in the last Office Action response filed. Applicant asserts that a representative number of species has been described to support the claimed genus.

The Examiner cites several cases to support the statement that a lack of written description arises if the specification does not allow one of ordinary skill in the art to immediately envisage the claimed invention. The Examiner cites *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) for the holding that a "laundry list" disclosure does not provide written description support for every species of a genus. Applicant asserts that this holding is not relevant to the claimed invention because Applicant is claiming a genus of nucleic acids, not a specific species. The specification does not constitute a laundry list of unrelated nucleic acids. Rather, the specification explicitly teaches the genus of claim 12. The Examiner cites *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) and *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) for the holding that the specification must clearly disclose the claimed invention. These cited cases relate to claiming a specific species based on a disclosure of a broad genus in the specification. Applicant asserts that this holding is not relevant to the claimed invention because Applicant is claiming a genus of nucleic acids, not a specific species. Furthermore, as outlined above, the specification does clearly and specifically describe the claimed genus of nucleic acids. In reading the specification and claims of the instant application, one of ordinary skill in the art would be able to immediately envisage the claimed invention.

To the extent that the Examiner has addressed the amended claims, the primary concern appears to be whether the CpG nucleic acids of the claimed invention are immunostimulatory. To this end, Applicant details various references that document the immunostimulatory activity of the claimed nucleic acids. Applicant refers to Krieg (Chapter 7: Ernst Schering Research Foundation Workshop, 2001, 30:105-18), cited in the IDS filed on October 31, 2007. Table 1, on page 107 of Krieg provides a list of oligodeoxynucleotide (ODN) sequences and indicates that cytokine production and B cell proliferation were stimulated when mouse spleen cells were cultured with these ODN. For example, ODN 1916 has the sequence TCCTGACGTTGAAGT, and exhibits a strong cytokine and B cell response, indicating the immune stimulatory properties of this nucleic acid. Applicant notes that this nucleic acid belongs to the genus of nucleic acids described in claims 12, 53 and 54. Also in Table 1 of Krieg, ODN sequences 1918, 1921 and 1938 belong to the genus of nucleic acids described in claim 12, and also correspond exactly to sequences that are listed in the instant sequence listing. ODN 1918 from Krieg corresponds to the instant SEQ ID NO:161, ODN 1921 from Krieg corresponds to the instant SEQ ID NO:164, and ODN 1938 of Krieg corresponds to the instant SEQ ID NO:181. Thus this reference demonstrates that multiple species from the claimed genus have been demonstrated to be immunostimulatory.

Applicant also refers the Examiner to USP 6,194,388 (Krieg et al.), issued on February 27, 2001. Column 10, paragraph 3 of USP 6,194,388 discusses optimal flanking bases surrounding a CpG in an immunostimulatory ODN. The "optimal stimulatory motif" was found to be two purine residues preceding the CpG and two pyrimidine residues following the CpG. Table 1, in column 11 of USP 6,194,388, lists ODN sequences and their corresponding stimulation index, which is indicative of their ability to induce B cell stimulation and IgM secretion. Applicant notes that many of the ODN sequences listed in Table 1 correspond to the instantly claimed genus of nucleic acids, and in some instances correspond exactly to sequences from the instant application. For example, ODN 2 in Table 1 corresponds to the instant SEQ ID NO:394, ODN 2a corresponds to the instant SEQ ID NO:703, ODN 3D corresponds to the instant SEQ ID NO:388, ODN 3Da corresponds to the instant SEQ ID NO:584, ODN 3Db corresponds to the instant SEQ ID NO:720, and ODN 3Dg corresponds to the instant SEQ ID NO:594. Thus the data from USP 6,194,388 indicate that multiple species from the claimed genus are immunostimulatory.

Applicant asserts that sufficient structural description of the necessary and common structural features of the claimed genus of nucleic acids has been provided. Applicant has provided over 200 species to represent the claimed genus and Applicant has indicated that multiple species of the claimed genus have been demonstrated to be immunostimulatory. Applicant considers that the written description requirement is satisfied.

Applicant further notes that claim 12 has been amended to remove the words “or preventing” from the preamble of this claim.

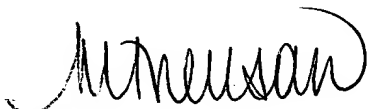
Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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Date: April 21, 2008
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